Robert Bosch Healthcare Systems, Inc.

November 07, 2013

NOV 14 2013

510(k) Summary

REGULATORY AUTHORITY

Safe Medical Devices Act of 1990, 21 CFR 807.92

COMPANY NAME/CONTACT

Louise Musante
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Robert Bosch Healthcare Systems, Inc.
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NAME OF DEVICE

Trade name: Bosch Blood Pressure Monitor (BP5000 BT)

Device: System, measurement, blood-pressure, non-invasive

Regulation Description: Noninvasive blood pressure measurement system

Product Code: DXN

Regulation Number: 21 CFR 870.1130

Device Class: Class II

PREDICATE DEVICE

Trade name: BPW120 Blood Pressure Meter

Model #: BPW120

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510(k) submitter/holder:

IDT Technology Limited
Block C, 9/F., Kaiser Estate, Phase 1
41 Man Yue Street
Hunghom, Hong Kong
China, 300193

510(k) #: K050083

DEVICE DESCRIPTION

The Bosch Blood Pressure Monitor (BP5000 BT) is an upper arm, non-invasive, blood pressure device, designed for home use. It is a simple device designed to measure a patient's systolic and diastolic pressures, as well as pulse rate using the oscillometric measuring method.

The Bosch Blood Pressure Monitor (BP5000 BT) has a voice prompt function and a memory function. There are five available languages to choose from (US English, UK English, Spanish, French and German). The BP5000 BT can store up to 42 measurements, including their date and time stamp, in its memory. By pressing the memory button on the device, the last blood pressure measurement and pulse rate is displayed on the LCD screen and announced by the voice prompt. The volume can be adjusted by pressing the volume button.

The Bosch Blood Pressure Monitor (BP5000 BT) is also designed to connect wirelessly, via Bluetooth, to a Bosch or Continua compliant telehealth patient interface. The connection is made automatically when the telehealth device prompts the patient to take their blood pressure measurement. Once the measurement is complete, the Bluetooth symbol on the blood pressure monitor will flash, indicating that the measurement is being transferred to the telehealth device. If Bluetooth is disabled, the BP5000 BT will store the measurements in its memory and will transmit all the stored data to the telehealth device once Bluetooth has been enabled.

INDICATION FOR USE STATEMENT

The Bosch Blood Pressure Monitor (BP5000 BT) is intended for use by adults to measure systolic and diastolic pressures, as well as pulse rate, by the oscillometric method, with a telehealth system or for home use.

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SUBSTANTIAL EQUIVALENCE COMPARISON

The Bosch Blood Pressure Monitor (BP5000 BT) is substantially equivalent to the predicate device, BPW120 Blood Pressure Meter (K050083), based on a comparison of the intended use and technological characteristics.

PERFORMANCE TESTING

Verification and validation testing activities were conducted to establish the performance, functionality and reliability characteristics of the BP5000 BT. Testing included electrical safety, EMC environmental testing, unit testing, and functional testing. A risk hazard analysis and design FMEA were performed and identified risks were mitigated through design or labeling. The Bosch Blood Pressure Monitor (BP5000 BT) performed as intended.

CONCLUSION

Robert Bosch Healthcare Systems, Inc. has determined that the Bosch Blood Pressure Monitor (BP5000 BT) is substantially equivalent in intended use and technological characteristics to the BPW120 Blood Pressure Meter (K050083). The Bosch Blood Pressure Monitor (BP5000 BT) therefore meets the Federal Food, Drug and Cosmetic Act criteria for 510(k) clearance of this device.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

November 14, 2013

Robert Bosch Healthcare Systems, Inc.
Ms. Louise Musante
Supervisor of Regulatory Affairs
2400 Geng Road, Suite 200
Palo Alto, CA 94303

Re: K131026
Trade/Device Name: Bosch Blood Pressure Monitor, Model BP5000 BT
Regulatory Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (Two)
Product Code: DXN
Dated: October 3, 2013
Received: October 4, 2013

Dear Ms. Musante:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: _____

Device Name: BP5000 BT

Indications for Use:

The Bosch Blood Pressure Monitor (BP5000 BT) is intended for use by adults to measure systolic and diastolic pressures, as well as pulse rate, by the oscillometric method, with a telehealth system or for home use.

Prescription Use _____ AND/OR Over-The-Counter Use __X__
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by Owen P. Faris -S
Date: 2013.11.14 10:20:49 -05'00'